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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS

ACTION: Notice

SUMMARY: The inventions listed below are owned by an agency of the U.S.

Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

FOR FURTHER INFORMATION: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852-3804; telephone: 301-496-7057; fax: 301-402-0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Device for Non-Surgical Tricuspid Valve Annuloplasty

Description of Technology: This is a non-surgical tricuspid annuloplasty to treat functional tricuspid valve regurgitation, meaning regurgitation with intact valve leaflets. The device is delivered using novel catheter techniques into the pericardial space and positioned along the atrioventricular groove. A compression member is positioned along the tricuspid annular free wall and tension applied through a variably-applied tension element. In the best embodiment, the compression member has an M shaped portion with at least two inflection points between the segments of difference curvatures.

Potential Commercial Applications:

- Valvular heart disease
- Tricuspid valve annuloplasty

Competitive Advantages:

- Non-surgical catheter treatment of valve disease
- Tricuspid valve

Development Stage:

- Prototype
- Pre-clinical
- In vitro data available
- In vivo data available (animal)

Inventors: Robert Lederman, Kanishka Ratnayaka, Toby Rogers (NHLBI)

Intellectual Property: HHS Reference No. E-027-2013 – US Provisional Patent

Application 61/785,652 filed 14 Mar 2013

Related Technologies: HHS Reference Nos. E-112-2010; E-108-2010; E-165-2008; E-249-2006/0, /1, /2

Licensing Contact: Michael A. Shmilovich, Esq., CLP; 301-435-5019;
shmilovm@mail.nih.gov

Collaborative Research Opportunity: The NHLBI is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize technologies for functional tricuspid valve regurgitation. For collaboration opportunities, please contact Peg Koelble at koelblep@nhlbi.nih.gov.

Urine-based Diagnostic Assay for the Early Detection of Cancer

Description of Technology: NIH scientists have identified a panel of metabolite biomarkers capable of predicting the onset of cancer with an accuracy approaching 100%. Concerted changes in the levels of select amino acid, nucleic acid and methylation metabolites in the urine of mice strongly correlated with tumor formation and reflected the progressive derangement in their underlying biochemical pathways. Researchers have developed high-throughput screening methodology to quantify the levels of these metabolites in biological samples for the purposes of assessing cancer risk, determining disease prognosis and monitoring response to therapy. While applicable to many cancers, use of this technology for the detection of colorectal cancer represents a first-in-class diagnostic for this particular disease.

Despite therapeutic advances, colorectal cancer remains a significant clinical burden in terms of morbidity and mortality. Early detection is a key predictor of treatment outcome; however, current diagnostic methods are unsuitable for widespread

implementation. The ability to analyze noninvasively obtained patient samples in a high-throughput manner suggests that this technology is well positioned to serve as a population-level screening tool for the early detection of many cancers, including, colorectal.

Potential Commercial Applications:

- A diagnostic screen for the detection of colorectal and other cancers.
- Assay to monitor response to therapy and disease recurrence.

Competitive Advantages:

- Non-invasive sample collection (e.g., urine specimen).
- Metabolite profiling can be performed on an ELISA platform.
- High predictive accuracy.

Development Stage:

- Pre-clinical
- In vivo data available (animal)

Inventors: Soumen K. Manna, Kristopher W. Krausz, Frank J. Gonzalez (NCI)

Intellectual Property: HHS Reference No. E-020-2013/0 – US Application No.

61/755,891 filed 23 Jan 2013

Licensing Contact: Sabarni Chatterjee, Ph.D., MBA; 301-435-5587;

chatterjeesa@mail.nih.gov

Collaborative Research Opportunity: The National Cancer Institute, Laboratory of Metabolism, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize a non-

invasive assay for the detection of colorectal cancer. For collaboration opportunities, please contact John D. Hewes, Ph.D. at hewesj@mail.nih.gov.

User-friendly, Powerful Software for Analyzing ChIP-Seq Data

Description of Technology: The present invention provides a user-friendly software, called PAPST (Peak Assignment and Profile Search Tool for ChIP-Seq), for bench scientists to work with ChIP-Seq data in seconds, allowing the scientists to screen genes against multiple genomic features with ease and efficiency previously not realized. Furthermore, PAPST may be used to identify genes of special significance in a wide variety of biological and biomedical fields, which could lead the discovery of disease-associated genes and the development of therapeutic methods for human diseases. Lastly, this powerful, easy-to-use software does not require any special computation expertise.

Potential Commercial Applications:

- Genomic analysis.
- Drug target identification.

Competitive Advantages:

- Easy to use.
- Fast.
- Either a stand-alone software or as an add-on to existing commercial software.

Development Stage:

- Prototype
- Pilot

Inventors: Paul W. Bible (NIAMS), Hong-Wei Sun (NIAMS), Yuka Kanno (NIAMS), Lai Wei (NEI)

Publications:

1. Yang XP, et al. Opposing regulation of the locus encoding IL-17 through direct, reciprocal actions of STAT3 and STAT5. *Nat Immunol.* 2011 Mar;12(3):247-54. [PMID 21278738]
2. Yamane A, et al. Deep-sequencing identification of the genomic targets of the cytidine deaminase AID and its cofactor RPA in B lymphocytes. *Nat Immunol.* 2011 Jan;12(1):62-9. [PMID 21113164]
3. Ghoreschi K, et al. Generation of pathogenic T(H)17 cells in the absence of TGF-beta signalling. *Nature.* 2010 Oct 21;467(7318):967-71. [PMID 20962846]

Intellectual Property: HHS Reference No. E-008-2012/0 – Research Tool. Patent protection is not being pursued for this technology.

Licensing Contact: Michael A. Shmilovich, Esq., CLP; 301-435-5019; shmilovm@mail.nih.gov

Collaborative Research Opportunity: The Biodata Mining & Discovery Section of NIAMS is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize PAPST (Peak Assignment and Profile Search Tool for ChIP-Seq). For collaboration opportunities, please contact Hong-Wei Sun at 301-496-0016 or sunh1@mail.nih.gov.

Antimalarial Inhibitors that Target the Plasmodial Surface Anion Channel (PSAC) Protein and Development of the PSAC Protein as Vaccine Targets

Description of Technology: There are two related technologies, the first being small molecule inhibitors of the malarial plasmodial surface anion channel (PSAC) and the second being the PSAC protein itself as a vaccine candidate. The PSAC protein is produced by the malaria parasite within host erythrocytes and is crucial for mediating nutrient uptake. In vitro data show that the PSAC inhibitors are able to inhibit growth of malaria parasites, have high specificity, and low toxicity. Portions of the PSAC protein are found on the outer surface of infected host erythrocytes and the protein was recently shown to be encoded by the *clag3* gene. This discovery opens the possibility of developing the PSAC protein as a potential vaccine candidate against malaria.

Potential Commercial Applications:

- Antimalarial drugs
- Malaria vaccine

Competitive Advantages:

- Novel target against malaria
- Small molecule inhibitors of PSAC inhibit malarial parasite growth, have low toxicity, and high specificity
- PSAC protein is exposed on the surface of the infected host erythrocytes, making it an attractive vaccine candidate

Development Stage:

- Early-stage
- Pre-clinical
- In vitro data available

Inventor: Sanjay Desai (NIAID)

Publications:

1. Pillai AD, et al. Solute restriction reveals an essential role for clag3-associated channels in malaria parasite nutrient acquisition. *Mol Pharmacol.* 2012 Dec;82(6):1104-14. [PMID 22949525]
2. Desai SA. Ion and nutrient uptake by malaria parasite-infected erythrocytes. *Cell Microbiol.* 2012 Jul;14(7):1003-9. [PMID 22432505]
3. Nguitragool W, et al. Malaria parasite clag3 genes determine channel-mediated nutrient uptake by infected red blood cells. *Cell.* 2011 May 27;145(5):665-77. [PMID 21620134]
4. Pillai AD, et al. A cell-based high-throughput screen validates the plasmodial surface anion channel as an antimalarial target. *Mol Pharmacol.* 2010 May;77(5):724-33. [PMID 20101003]

Intellectual Property: HHS Reference No. E-145-2011/0 – International PCT Patent Application No. PCT/US12/33072 filed 11 Apr 2012

Related Technology: HHS Reference No. E-202-2008/0 – Patent family filed in the U.S., Europe, Brazil, India, and China

Licensing Contact: Kevin W. Chang, Ph.D.; 301-435-5018;
changke@mail.nih.gov

Collaborative Research Opportunity: The National Institute of Allergy and Infectious Diseases is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize Antimalarial Inhibitors that Target the Plasmodial Surface Anion Channel (PSAC) Protein. For

collaboration opportunities, please contact Dana Hsu at dhsu@niaid.nih.gov or 301-451-3521.

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Date

Richard U. Rodriguez,
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Division of Technology Development and Transfer
Office of Technology Transfer
National Institutes of Health

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